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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,490	09/17/2003	John F. Boylan	ACS 65471 (2133XXD)	4845

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FULWIDER PATTON
6060 CENTER DRIVE
10TH FLOOR
LOS ANGELES, CA 90045

EXAMINER

MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
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3734

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/664,490	Applicant(s) BOYLAN ET AL.	
	Examiner Michael G. Mendoza	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 32-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 32-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Allowable Subject Matter

1. The indicated allowability of claims 1-5 are withdrawn in view of the newly discovered reference(s) to Gray et al. 6461370. Rejections based on the newly cited reference(s) follow.

Claim Objections

2. Claim 34 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 34 for does not further limit independent claim 32. Claim 34 broadens claim 32. Claim 32 has the limitation of only a portion of the strut assembly and claim 34 has the limitation of the entire strut assembly.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 34 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. As to claim 34, it is unclear how both only a portion of the strut assembly and the entirety of the strut assembly could be coated with polymeric material.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 32, 33, and 36-43 are rejected on the ground of nonstatutory

obviousness-type double patenting as being unpatentable over claims 1-8 of U.S.

Patent No. 6702834. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are merely broader than the patent claims. The structural limitations set forth in claims 32, 33, and 36-43 of the instant application are also claimed in the patent, e.g., a shaft member having a distal and a proximal end; a filtering assembly; an expandable strut; a filter; and a layer of polymeric material deposited on the proximal struts. Because the claim states that the polymeric material is deposited on the proximal struts it reads on the limitation of only on portions of the strut. The portions being the proximal struts. Because the claim states that the polymeric material is deposited on the proximal struts it reads on the

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limitation of only on regions that experience low strain. The specification of the instant application defines the area of high strain to be the deployment member and the area of low strain being the struts.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

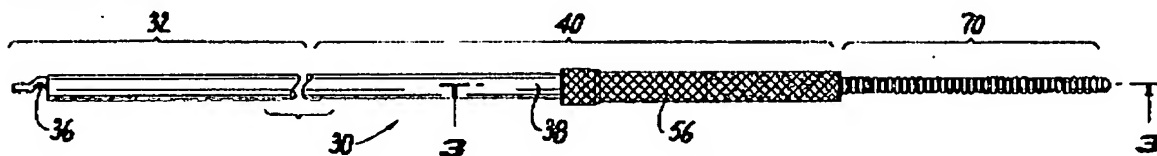
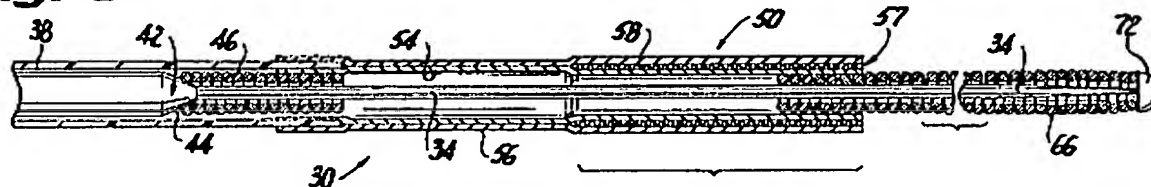
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Gray et al. 6461370

10. Gray et al. teaches an embolic protection device for capturing embolic debris released into a body vessel of a patient, comprising: a shaft member having a distal end, a proximal end and a stop fitting; a filtering assembly rotatably mounted on the shaft member near the distal end, the filtering assembly including an expandable strut assembly and a filter attached to the strut assembly, the filtering assembly being mounted on an outer tubular member which is coaxially disposed over an inner tubular member having a length shorter than the outer tubular member, wherein one end of the inner tubular member is fully capable of abutting against the stop fitting; wherein the shaft member is a guide wire and includes a distal spring tip coil, the spring tip coil serving as the stop fitting; wherein each of the inner and outer tubular members has a

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proximal end and a distal end and the guide wire includes a second stop fitting in an abutting relationship with the proximal ends of the outer and inner tubular members; and where the outer tubular member extends over a portion of the spring tip coil of the guide wire.

Fig. 2**Fig. 3**

11. Claims 32, 33, and 36-39, and 41-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Huter et al. 6511496 as evidenced by Bachinski et al. 5800525.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

12. As to claims 32, 33, 38, 41, and 43, Huter et al. teaches an embolic protection device for capturing embolic debris released into the body vessel of a patient, comprising: a shaft member; a filtering element including an expandable strut assembly and a filter attached to the strut assembly; a layer of polymeric material deposited only

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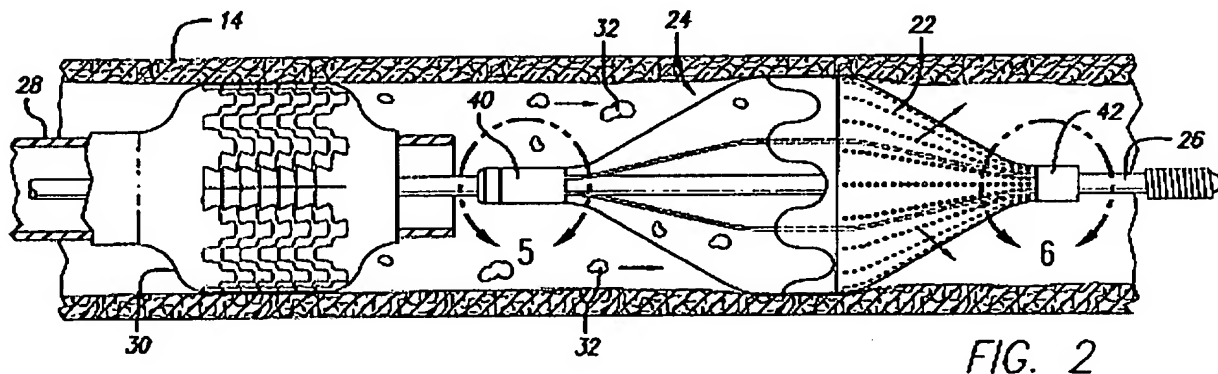
on portions of the strut assembly proximal to the filter; wherein the polymeric material is selected from the group consisting of PTFE and polyimide; and wherein the expandable strut assembly is made from a material having self-expanding properties (col. 6, lines 36-37).

13. Huter et al. teaches depositing a polymeric material only on the external surface of the strut (col. 7, lines 26-29). The filter is placed on the external surface of the strut. The external surface of the strut is more proximal to the filter than the internal surface of the strut. Therefore, Huter et al. teaches the limitation of only on portions of the strut assembly proximal to the filter.

14. As to claim 39, Huter et al. teaches the embolic protection device of claim 38, wherein the coating substance is a hydrophilic substance. Huter et al. coating with PTFE. PTFE is a hydrophilic substance as evidenced by Bachinski et al. (col. 3, lines 46-51).

15. As to claims 36, 37, and 42, Huter et al. teaches an embolic protection device for capturing embolic debris release into the body vessel of a patient, comprising: a shaft member; a filtering element including an expandable strut assembly and a filter attached to the strut assembly; the expandable strut assembly having regions which experience high strain and regions which experience low strain; a layer of polymer material deposited only on the regions which experience low strain; wherein the polymeric material is selected from the group consisting of PTFE and polyimide (col. 4, lines 15-37); and wherein the expandable strut assembly is made from a material having self-expanding properties (col. 6, lines 36-37).

16. The specification of the instant application defines the area of high strain to be the deployment member and the area of low strain being the struts (pg. 51, lines 19-24). Huter et al. teaches coating only the struts (col. 7, lines 15-31). Therefore, Huter et al. teaches the limitation of a layer of polymer material deposited only on the regions which experience low strain.



Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grey et al.

19. Gray et al. teaches the embolic protection device of claim 2 except for wherein the outer and inner tubular member are made from polyimide. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use polyimide, since it has been held to be within the general skill of a worker in the art to

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select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416. Furthermore, Gray et al. teaches that parts of the device are made from polyimide (col. 3, lines 55-56).

20. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huter et al. in view of Bachinski et al.

21. Huter et al. teaches the embolic protection device of claim 38. It should be noted that fails to teach wherein the coating substance is heparin. Huter et al. teaches the used of PTFE.

22. Bachinski et al. teaches a device with a common coating of PTFE. Bachinski et al. also teaches an alternative coating of heparin (col. 3, lines 48-51). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use heparin as an obvious alternative to PTFE for providing a smooth biocompatible surface for preventing clotting (col. 3, lines 52-56).

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Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

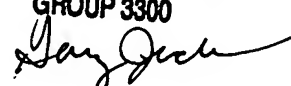
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571) 272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MM

4/11/2006

GARY JACKSON
PRIMARY EXAMINER
GROUP 3300

4-14-2006